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IN THE

Supreme Court of the United States

October Term, 1963

No. 833

SIDNEY STEINSCHREIBER, doing business as SID-CAPS LABORATORIES, JOHN P. CALISE, WEST-CHESTER BLOOD SERVICE, INC.,

Petitioners,

against

UNITED STATES OF AMERICA,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

[redacted]

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Petitioners,

against

UNITED STATES OF AMERICA,
Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITIONERS' BRIEF

To The Supreme Court of the United States:

Petitioners pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit entered in the above entitled case on January 17, 1964, hereto annexed and marked "Appendix A".

CITATIONS TO OPINIONS BELOW

Subsequent to indictment (*vide* Appendix "B" annexed hereto), petitioners made motions to dismiss same predicated upon a failure of the Government to set forth an offense chargeable under the statute under which said indictment was drawn; the motion was denied by District Judge Sylvester J. Ryan, in *U. S.* v. *Steinschreiber*, reported at 218 F. Supp. 426 (S. D. N. Y., 1962), and his opinion was reproduced in Appellants' Appendix, pp. 5A-8A. Petitioners were permitted to register continuing objections to the admission of Government's expert testimony at the trial, and at the close of Government's case petitioners moved to dismiss indictment. The motion was denied and judgment rendered against petitioners by District Judge Harold R. Tyler, Jr., in *U. S.* v. *Steinschreiber et al.*, 219 F. Supp. 373 (S. D. N. Y., 1963), reproduced opinion in full, in Appellants' Appendix, pp. 9A-33A.

JURISDICTION

The criminal offense charged was prosecuted in the United States District Court for the Southern District of New York, based upon a statute regulating the production of biological products under the commerce clause of the Constitution of the United States (Appellants' Appendix, pp. 91A, 93A, 95A, 97A, 99A). Upon conviction, appeal was taken to the United States Court of Appeals for the Second Circuit, where judgment was affirmed *per curiam*, based upon the opinion of the Trial Court (*vide* Appendix "A"). This petition for a writ of certiorari followed.

QUESTIONS PRESENTED FOR REVIEW

1. Does the statute include, within its express terms, the activities for which the petitioners have been indicted and convicted?

2. Was it error for the District Judge to admit concededly expert testimony by Government witnesses for the purpose of defining the terms and scope of a penal statute?

STATUTE INVOLVED

The prosecution was based upon the Act of July 1, 1944, c. 373, Title III, section 351, 58 Stat. 702, as amended by the 1953 Reorganization Plan No. 1, sections 5 and 8, eff. April 11, 1953, 18 F. R. 2053, 67 Stat. 631, which has been codified as Title 42 U. S. Code, sec. 262. (pp. 91A, 93A, 95A, 97A, 99A, Appellants' Appendix.)

STATEMENT

Petitioners were indicted by the Grand Jury in and for the Southern District of New York (62 Cr. 310) filed April 2, 1962. Thereafter, a superseding Indictment was found against petitioners herein (62 Cr. 797) on August 16, 1962 and subsequently, petitioners were indicted on still another superseding Indictment (62 Cr. 919) on October 10, 1962. The petitioner Steinschreiber was charged in the First Count thereof, with conspiracy to violate the Biological Products Control Act (Sec. 262, T. 42, U. S. Code, and Sec. 371, T. 18, U. S. Code), and in the remaining Counts of engaging in the preparation and sale, in interstate and foreign commerce, of normal human blood plasma, and in

falsely labeling the same, without a license issued by the Secretary of the Department of Health, Education and Welfare. Petitioners Calise and Westchester Blood Service, Inc., were only charged with conspiracy under the First Count to furnish petitioner Steinschreiber with liquid human blood and contributing to the cost of manufacturing this human blood into normal human blood plasma.

Petitioner Steinschreiber moved to dismiss the Indictment (62 Cr. 310) on the ground that the offense as charged was not included within the prohibition of the statute (42 U. S. C. 262), and, that said statute, if it did include the offenses as charged, was unconstitutional because of vagueness. Petitioner Calise joined in the motion, which was denied by Chief Judge Sylvester J. Ryan on May 25, 1962 and thereafter motions to dismiss Indictment (62 Cr. 919) were likewise denied on same grounds by Judge Ryan on October 26, 1962.

The final superseding Indictment (62 Cr. 919) was moved for prosecution. The cause proceeded to trial on April 8, 1963, before Judge Harold R. Tyler, Jr., sitting without a jury in accordance with petitioners' due consent thereto.

In the course of the trial, the Court admitted expert testimony on behalf of the Government concerning the intent, construction and definition of the statutory provisions. To this, petitioners herein made due and timely objection, at many points throughout the trial. The trial was concluded on the 26th day of April, 1963. Petitioners renewed their respective motions to dismiss the Indictment at the close of the entire case; decision was reserved. Thereafter, on the 1st day of July, 1963, in accordance with its written opinion (28th day of June, 1963) and supple-

mental opinion (July 29, 1963), the Court found petitioner Steinschreiber guilty on all Counts except the Ninth, which was dismissed on motion, and petitioners Calise and Westchester Blood Service, Inc., were found guilty on the First Count. The Court pronounced sentence on petitioner Steinschreiber on the 2nd day of August, 1963, and sentenced him to a term in prison for ninety (90) days with a two-year probation commencing at the end of the ninety-day term; petitioner Calise was sentenced to a term of sixty (60) days imprisonment, and upon completion of the term of imprisonment, to two (2) years probation and Westchester Blood Service, Inc., was fined $500.00. Motions of the petitioners herein to set aside the verdict of the Court were denied.

Thereafter, the petitioners were re-sentenced on the 20th day of August, 1963, wherein petitioner Steinschreiber was sentenced to three (3) months imprisonment on Counts 1 to 8 and 10 to 15, concurrently, and execution of sentence was suspended on Count one and probation of two (2) years to commence after expiration of sentence on Counts 2 to 8 and 10 to 15. Petitioner Calise received a re-sentence to six (6) months confinement, of which two (2) months were to be spent in confinement, and the balance of four (4) months to be suspended, with two (2) years of probation. The renewal of the motions of the petitioners to set aside the verdict of the Court was denied.

The appeal was argued before the Court of Appeals for the Second Circuit on January 9, 1964; the Court rendered its *per curiam* opinion and affirmed the judgment of the District Judge on January 17, 1964. (Appendix "A" herein). No motion for rehearing has been made to the Court of Appeals for the Second Circuit. Petitioners were

permitted to remain on bail of $2000.00 pending a determination of the instant Petition.

Petitioners do not dispute the facts as outlined in the opinion of Tyler, D. J., and so far as the facts are material to the issues of law raised in this petition, are willing to follow the same procedure utilized in the Court of Appeals, namely they are willing to accept the statement of facts given in the opinion of the District Judge, as reproduced in Appellants' Appendix, pp. 7A-33A.

REASONS FOR GRANTING THE WRIT OF CERTIORARI

1. Despite the relative antiquity of the statutory provisions, this is a case of first impression in which the existing decision of the District Court does not adequately resolve the questions of statutory interpretation.

The original enactment concerning biological products was passed in 1902, at a time when the use of whole human blood transfusions was highly dangerous to human life, and normal human blood plasma was unknown to medical science. After the successful use of normal human blood plasma in the period 1935-1944, the 1902 statute was reenacted in what is materially the same form, in 1944. Thus the regulation of biological products today is substantially identical, in its statutory basis, with the regulatory plan that was originally enacted in 1902. (Appellants' Appendix, pp. 90A, 92A, 94A, 96A, 98A.)

Despite the existence of this body of statutory law, there has never before been a prosecution, under this statute, of

a person accused of preparing or selling normal human blood plasma, without a license from the Public Health Service. Now, nearly thirty years after the discovery of normal human blood plasma and its medical uses, and twenty years after the re-enactment of the 1902 statute there arises the first case of a prosecution for such a breach of the statutory provisions.

The difficulty of interpreting this statute is vastly increased by the fact that neither the Government nor Petitioner's counsel could find a single case defining the operative words in the statute; for this reason resort was had to decisions defining those words as contained in other Federal statutes.

In writing his opinion the learned District Judge inadvertently overlooked the historical fact, that the medical uses of blood were nearly totally unknown in 1902, and imputed to Congress an intention to regulate the preparation of normal human blood plasma. He also erred in concentrating his attention upon the provision of the Public Health Service Regulations, 42 C.F.R. 73.1 (i) (5). (ii) which mentions blood plasma but not *human* blood plasma (Appellants' Appendix, pp. 102A, 103A); in so limiting the scope of his inquiry he leaves unexplained the question of why there is now in the Code of Federal Regulations, not only the biological products regulation from which he quoted, but also regulations for whole blood (human) and packed red blood cells (human)—*but no regulation concerning normal blood plasma (human)*! These oversights, although brought to the attention of the Court of Appeals, were affirmed by them without opinion. Unless certiorari is granted by this Court, they will continue to define Federal law in this area.

2. Petitioners have been deprived of their constitutional rights by an indictment and conviction predicated upon a statute which does not by its express terms, or its plain meaning, proscribe the activity in which they participated.

This Court recently considered a similar situation to that presented in this case, namely conviction upon an indictment which failed to charge an offense included within the scope of the statute, *Wright* v. *Georgia*, 373 U. S. 284, 83 S.Ct. 1240, 10 L.Ed. 2d, 349 (1963). In that case the conviction was for an offense allegedly against the breach of the peace statute, but the indictment did not charge an offense within the limits of that admittedly broad statute; this Court reversed the conviction.

The instant case entails a similar variance between statute and indictment; it presents a case in which petitioners were deprived of their constitutional rights, not by an unconstitutionally vague statute, but rather by a prosecution founded upon an unconstitutionally broad interpretation of the statute. Such a case makes the strongest appeal that the Supreme Court exercise its supervisory powers, for in refusing to grant a motion to dismiss such an indictment, the Courts of the United States are made party to an unconstitutionally broad interpretation of a penal statute. The unconstitutionality involved here is not the action of Congress, but rather the proceeding of the United States Attorney as approved by the Federal judiciary.

A. The statutory language, as interpreted in the indictment, is not adequate notice that the offense charged was prohibited by Congress.

Petitioners and the Government differ upon the scope of the terms, "Therapeutic serum • • • or analogous product • • •"; it is Petitioners' contention that the terms are so limited as to exclude, affirmatively, normal human blood plasma from their coverage. The Government, on the other hand, points to the alleged chemical similarities between "serum" and "blood plasma"; the continued "acquiescence" of the pharmaceutical industry in Public Health Service regulation of human blood plasma preparation; and upon the Petitioners' "knowledge" that the Public Health Service had customarily undertaken such "regulation" and "acceptance" of human blood plasma as a "therapeutic serum or analogous product."

As Petitioners argued below, there is strong historical evidence against the Government's assertions (*vide* hereto Appendix "C" Excerpts from Steinschreiber Briefs). Failure to comply with trade custom alone, cannot subject Petitioners to criminal sanctions for local and trade custom has been denied any potency in Federal criminal law, *Burnett* v. *U. S.*, 222 F. 2d 426 (6th Cir., 1955), *Smith* v. *U. S.*, 188 F. 2d 969 (9th Cir., 1951), *U. S.* v. *Weinberg*, 226 F. 2d 161 (3rd Cir., 1955). It is further submitted that Petitioners' knowledge of the statute is presumed as a matter of law; their knowledge is not material to the question of what the statute means.

B. The Courts below have unconstitutionally broadened an outdated statute in an effort to include, within its terms, the activities of petitioners; in doing so, they have exceeded their judicial powers and have trespassed upon the legislative powers constitutionally vested in Congress.

This is a hard case that is destined to make bad law if certiorari is not granted. Clearly some supervision of human blood plasma production is in the public interest and within the powers of Congress. Judges being human share the all too human tendency to picture themselves as victims of a contaminated blood transfusion. While Petitioners state, in passing, that no deleterious results have been noted because of their activities, they strongly urge upon this Court that the principle of the separation of legislative from judicial powers requires that regulation of normal human blood plasma preparation must proceed *not* from the decision of a Judge, but rather from a statute of Congress. Unpopular though his decision may be and may seem to him, personally, it is the solemn duty of a Federal court to refrain from taking action where Congress has failed to act with regard thereto.

The Government persuaded the Courts below that by reenacting the Biological Products Control Act in 1944, and by making appropriations for the Public Health Service from 1939 to the present date, Congress acquiesced in that agency's regulation of normal human blood plasma. In this contention the Government is unsupported by any historical evidence; in fact its position is negated by a close inspection of the Congressional committee report and the appropriation acts (*vide* Appendix "C" herein). Ir-

quendo, even if such could be considered the intention of Congress would this have been adequate notice under the void for vagueness doctrine laid down by this Court in *U. S.* v. *Cohen Grocery Co.*, 255 U. S. 81, 41 S. Ct. 298, 65 L. Ed. 516 (1921), *Lanzetta* v. *New Jersey*, 306 U. S. 516, 59 S. Ct. 618, 83 L. Ed. 888 (1939)?

Further proof of the antiquity of this statute is the crude technique of delegating authority to the Public Health Service, again derived from the 1902 statute. The delegation is one of authority to issue licenses pursuant to the statute, to establish standards of cleanliness in production, and to inspect establishments producing biological products; there is *no* delegation of authority to issue regulations defining the statutory terms *nor* to add new products as developed by medical science. It is the Government's erroneous contention, now adopted by the Courts below, that this is adequate delegation of authority upon which the Public Health Service may prescribe standards for new products *not* included *nor* defined within the scope of the statute.

C. The Government should not have been permitted to introduce its expert witnesses to interpret the terms and scope of the statute over due and timely objection.

Three expert witnesses submitted their personal opinions on Government's case, concerning the definitions of the terms "therapeutic", "serum", "plasma", and "analogous", *and, in their testimony*, further assured the Trial Judge that "normal human blood plasma was a product analogous to therapeutic serum." The Government argues that since the trial herein was before a Judge, without a

jury, no reversible error occurred. However Petitioner fails to understand why a Judge would not be as much influenced by the opinion of these testimonial experts as a jury would have been. What occurred in this case was the unlawful substitution of experts to delineate the intent, meaning, definition and construction of the Statute for the District Judge and prejudice his interpretation of the statute concerned. This cannot be countenanced in the annals of Federal criminal law administration.

3. There is no statute, nor any administrative regulation, proscribing the petitioners' alleged criminal activity.

As noted in 1(B), above, the statutory delegation of powers to the Public Health Service is in such terms as to render impotent any interpretive regulations by the Service. However even if the interpretive power is conceded to the Public Health Service, it is impossible to find any regulation of the Service which would serve as a warning to Petitioners that their anticipated activities were contrary to regulations.

A. The regulations do not contain a section providing for the regulation of normal human blood plasma production.

The Government bottoms its case upon that portion of the Regulations which related to therapeutic serums, despite the fact that there are separate and distinct regulations concerning whole blood (human) and packed red blood cells (human), 42 C.F.R. 73.300 *et seq.*, 42 C.F.R. 73.320 *et seq.* The Government fails to explain why a simi-

lar regulation has *not* been issued for normal blood plasma (human). If normal human blood plasma is encompassed within the terms "therapeutic serum", why did the Public Health Service find it necessary to issue separate and distinct regulations concerning the source of normal human blood plasma—i.e. whole blood (human)—, and for one of the products which, like normal human blood plasma, is obtained from whole blood (human)?

It should be noted that in his opinion the learned Trial Judge referred to 42 C.F.R. 73.1 (i) (5) (ii) which refers to "* * * whole blood or plasma", but which does not specify that it is *human*, as contradistinguished from animal blood, which is intended! The Government strenuously argued below, by its counsel and its experts, that a human being is an animal; if this contention is accepted, the Trial Judge's conclusion concerning the regulatory provision may be correct. Petitioners do not now urge this Court to review Darwin's theory of evolution, but deferentially submit that Federal criminal law will be in a sorry state, indeed, when lawyers and judges identify humans with animals for the purposes of administering the penal statutes.

B. Since there is no promulgated regulation concerning normal human blood plasma, petitioners could not have had notice, as a matter of law, that their activities were proscribed.

Only one document has been found to state the Public Health Service's attitude toward normal human blood plasma. It is an office memorandum which by the policy of the Service, printed upon the face of the memorandum, *is not to be made available generally.* (Govt's Appendix,

p. 254a, bottom of opposite page). It has *never* been printed in the Code of Federal Regulations! Such a document cannot be considered legally binding upon Petitioners, in fact it has no force whatsoever because it fails to meet the constitutional requirement of due notice of the scope of a penal statute! The document is mentioned here to indicate to the Court the haphazard techniques which the Public Health Service has used in the attempt to supervise the sanitary conditions under which blood plasma is prepared. (Govt's Exh. 62, p. 254a, Govt's Appendix). The Public Health Service has been totally negligent of the public interest in this regard. It has failed to seek or request Congress to pass a new statute or to amend the old statute. It has failed to issue a regulation concerning normal human blood plasma in the Code of Federal Regulations! It has now "cornered" individuals, who, in its opinion, have violated the "gentleman's agreement" between the Public Health Service and the "pharmaceutical industry." It has sought, and obtained, the assistance of the Attorney General's office in indicting and convicting these men; and in the process of obtaining the convictions, has prevailed upon the District Judge and the Court of Appeals, an appeal so effective, that it caused them to overlook the constitutional rights of the accused. Should the Public Health Service be permitted to make the Courts of the United States a party to their belated attempt to take circuitous action in this field without seeking the enactment of legislation by Congress?

CONCLUSION

The Court should, in the exercise of its supervisory powers, grant the petitioners a writ of certiorari for the purpose of reviewing the judgment of conviction and affirmance in the Courts below.

Respectfully submitted,

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APPENDIX "A"

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 245—September Term, 1963.

(Argued January 9, 1964 Decided January 17, 1964.)

Docket No. 28498

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

—v.—

SIDNEY STEINSCHREIBER, doing business as SIDCATS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC.,

Defendants-Appellants.

Before:

LUMBARD, *Chief Judge,*

KAUFMAN and MARSHALL, *Circuit Judges.*

Appeal from judgments of conviction entered in the United States District Court for the Southern District of New York, Harold R. Tyler, Jr., *J.*, sitting without a jury.

Affirmed.

Appendix "A"

ALBERT J. GAYNOR, Assistant United States Attorney, New York, N. Y. (Robert M. Morgenthau, United States Attorney for the Southern District of New York, Richard A. Givens, Charles A. Stillman and Robert J. Geniesse, Assistant United States Attorneys, New York, N. Y., on the brief), *for appellee.*

ABRAHAM S. ROBINSON, New York, N. Y. (Emanuel Thebner and Herbert Alan Johnson, New York, N. Y., on the brief), *for defendant-appellant Sidney Stainschreiber.*

ALEXANDER DREIBAND, New York, N. Y. (Dreiband, Bleecker & Silberman, New York, N. Y., on the brief), *for defendants-appellants John P. Calise and Westchester Blood Service, Inc.*

PER CURIAM:

The judgments below are affirmed on the opinion of Judge Tyler, reported at 219 F. Supp. 373 (S. D. N. Y. 1963).

APPENDIX "B"

Indictment—62 Cr. 919

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., HAROLD H. FISHER, KEMWORTH LABORATORIES, INC., and NORMAN CAPPEL,

Defendants.

COUNT ONE

The Grand Jury charges:

1. From on or about the 1st day of January, 1960 up to and including date of the filing of this indictment, in the Southern District of New York and elsewhere, SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., HAROLD H. FISHER, KEMWORTH LABORATORIES, INC., and NORMAN CAPPEL, defendants, unlawfully, wilfully and knowingly, did combine, conspire, confederate and agree together and with each other and with others to the Grand Jury unknown, to commit offenses against the United States, to wit, to violate Section 262 of Title 42, United States Code.

Appendix "B"

2. It was a part of said conspiracy that defendants HAROLD H. FISHER, KEMWORTH LABORATORIES INC., and NORMAN CAPPEL would manufacture and prepare and cause to be manufactured and prepared a product analogous to a therapeutic serum and applicable to the prevention, treatment and cure of diseases and injuries of man, to wit, dried normal human plasma, a biological product derived from whole blood, at establishments that did not then hold any applicable license issued by the Secretary of the Department of Health, Education and Welfare as required by Section 262 of Title 42, United States Code.

3. It was further a part of said conspiracy that defendants JOHN F. CALISE and WESTCHESTER BLOOD SERVICE, INC. would furnish liquid human plasma for manufacturing dried plasma at KEMWORTH LABORATORIES INC., and would contribute to the cost of manufacturing and of supplies therefor.

4. It was further a part of said conspiracy that defendant SIDNEY STEINSCHREIBER, doing business as SIDCAPS LABORATORIES, would cause the plasma described in paragraph 2 of this count to be sent, carried, and brought for sale from the States of New Jersey and Pennsylvania into the State of New York, and from the State of New York into foreign countries, to wit, Cuba, Israel, and other countries to the Grand Jury unknown, although said plasma was not propagated or manufactured and prepared at an establishment holding an applicable license issued by the Secretary of Health, Education and Welfare as required by Section 262 of Title 42, United States Code.

• • •

APPENDIX "C"

Excerpts From Steinschreiber Briefs

* * *

* * * The use of citrated whole blood, perfected in 1914, came into widespread use during the First World War (*Zimmerman & Howell, supra*, pp. 428, 431, R. 1345). The practical uses of dried and liquid human blood plasma were not in widespread application until 1940-1942, although some emergency use of human blood plasma had been made in the past decade. (See *N. Y. Chapter, American Red Cross, The Story of the Blood Donor Service*, p. 6; see also, R. 1305, Appendix, pp. 54a-55a.)

From the history of the use of blood plasma, we may conclude that Congress in 1902 had no intention of regulating the processing of either whole human blood, nor of normal human blood plasma. The learned District Judge inadvertently overlooked the historical facts outlined above when he imputed to Congress the intent to regulate blood plasma preparation in 1902 (see Opinion of Tyler, Jr., D. J. at Appendix p. 28a).

In the years between 1902 and 1944, a new product, normal human blood plasma, was introduced to the medical world (Appendix, pp. 54a, 55a, 60a-62a). Indeed, during the war years of 1940-1944, the use and urgent need for normal human blood plasma was widely known in the United States, and we must presume that Congressmen, as well as their fellow-citizens, were well aware of the importance of normal human blood plasma to the members of the armed forces who had been wounded in action. A glance at some statistics reflects that in January of 1944

the New York Chapter of the American Red Cross collected 39,400 pints of blood, and in March the Chapter collected 40,888 pints. In its Annual Report for the year 1943, the Public Health Service proclaimed the use of normal human blood plasma "* * * undoubtedly one of the greatest therapeutic agents of all time in emergency treatment" (H. R. Doc. 437, 78th Cong. 2nd Sess., 1943, p. 111).

It was in the midst of this nationwide effort to provide whole human blood and normal human blood plasma for the use of the armed forces, that Congress began its consideration of a proposed revision of the public health laws of the United States. The House Committee considering the revision and consolidation of the public health laws made certain changes "found necessary by long administrative practices," "the entire bill was carefully gone over," and then reported for consideration. 90 Cong. Rec. 4796 (1944) (Statement of Rep. Alfred D. Bulwinkle). Their comment upon the statute now in question is particularly revealing.

> Section 351, relating to the licensing of manufacturers of biologic products, would similarly be a reenactment of present law (42 U. S. C. 141-148) with only slight changes. The control would be extended to arsphenamine and other trivalent organic arsenic compounds, as has been done, though with less precision in appropriation acts. (H. R. Rept. 1364, 78th Cong., 2nd Sess. 1944).

No mention of human blood or human blood plasma! The only change that the Committee saw fit to recommend in this 1902 statute was the addition of another product

which it wished to bring within the licensing provisions of the new statute. Is it conceivable that Congress could have *forgotten* to consider normal human blood plasma? Is it not far more likely that while well aware of the contemporary use of normal human blood plasma, they felt that it was either too soon to license its production or that normal human blood plasma was *not* a biological product similar to the ones enumerated in the old statute, and that its regulation would require a new statute or a radical re-writing of the old statute? Does not the absence of any mention of whole human blood or its products present strongly persuasive evidence that this statute does *not* apply to normal human blood plasma, neither as enacted in 1902 nor as re-enacted in 1944? **(From pp. 4-6, Steinschreiber Brief)**

* * *

As discussed on pp. 1-3, *supra*, the 1944 re-enactment of the statute took place at a time when Congress would have been well aware of the use for blood plasma. Furthermore, Congress *did* change the statute to include a drug developed since 1902, a drug found particularly effective in the treatment and cure of a disease—syphilis. As noted by the Committee Report (pp. 2, 3), the drug inserted by the Committee was one which had previously been regulated under appropriation acts, presumably as an "analogous product." Despite the fact that the product was being regulated as an "analogous" product, Congress chose to make this regulation specific by including the article among the enumerated items **(From p. 12, Steinschreiber Brief)**.

* * *

Appendix "C"

The Government purports to find within Appropriation Acts and in the re-enactment of the 1902 statute, Congressional approval of the administration of the Biological Products Control Act, which administration, according to the Government, included the regulation of establishments engaged in the preparation and sale of normal human blood plasma.

If the Court will but look to the Appropriation Acts cited so conveniently by the Government on page 27 of its brief, it will find that these Acts contain *no* verbiage that supports the Government's contention of Congressional approval. As an example, the 1945 Appropriation Act, enacted two days before 42 U. S. C. 262, reads as follows:

> "National Institute of Health: * * * for regulating the propagation and sale of viruses, serums, toxins, and analogous products, including arsphenamine and other organic arsenic compounds analogous thereto; * * *" 58 Stat. 559.

In short, the Appropriation Act does indicate a Congressional intent in regard to arsphenamine, *but none whatsoever in regard to normal human blood plasma.* It is merely a recitation of the provisions of the Biological Products Control Act, as then in force, and lends absolutely no weight to the Government's position. It might be noted that the 1962 Appropriation Act, 75 Stat. 601, would be even less helpful to Government's attempt to bolster its case.

Apparently the Government finds no use for the Report of the Congressional Committee which considered the 1944 reenactment of the Biological Products Control Statute (quoted in full by appellant in his brief; p. 5). Is this not *the best evidence of Congressional intent in 1944?* **(From pp. 6, 7, Steinschreiber Reply Brief.)**

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In the Supreme Court of the United States

OCTOBER TERM, 1963

No. 833

SIDNEY STEINSCHREIBER, DOING BUSINESS AS SIDCAPS LABORATORIES, JOHN P. CALISE, WESTCHESTER BLOOD SERVICE, INC., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (II R. 310–311; Pet. App. A1–2) [1] is reported at 326 F. 2d 759. The opinions of the district court (I R. 5–8; 9–32; 33) are reported at 218 F. Supp. 426 and 219 F. Supp. 373.

JURISDICTION

The judgment of the court of appeals was entered on January 17, 1964 (II R. 312). The petition for a writ of certiorari was filed on February 14, 1964. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

[1] The record on file with the Clerk of this Court consists of the appendices to the briefs of the parties filed in the court of appeals. The appendix to petitioners' brief is designated "I R." and the appendix to the government's brief is denoted "II R."

QUESTIONS PRESENTED

1. Whether normal human blood plasma is a product "analogous to therapeutic serum" within the meaning of Section 351 of the Public Health Service Act.

2. Whether Section 351 of the Public Health Service Act is sufficiently clear and definite to sustain a criminal prosecution for its violation.

3. Whether the district court, sitting without a jury, properly allowed into evidence expert testimony that normal human blood plasma is a product "analogous to therapeutic serum."

STATUTE AND REGULATIONS INVOLVED

Section 351 of the Public Health Service Act, 58 Stat. 682, 702, as amended, 42 U.S.C. 262, provides in pertinent part:

> "(a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment hold-

ing an unsuspended and unrevoked license, issued by the Secretary as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Secretary not to sell, barter, or exchange the same.

(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid so as to falsify such label or mark.

* * * * *

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a

fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

42 C.F.R. 73.1 (1963 ed.) provides in pertinent part:

* * * * *

(i)(2) A therapeutic serum is the product obtained from the blood of an animal by removing the clot or clot components and the blood cells, and not intended for ingestion.

* * * * *

(i)(5) A product is analogous:

* * * * *

(ii) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum, and not intended for ingestion.

* * * * *

STATEMENT

After a trial by the court, sitting without a jury, petitioners were convicted in the United States District Court for the Southern District of New York of violation of Section 351 of the Public Health Service Act. This statute proscribes the transportation for sale, barter or exchange of enumerated biological products including "therapeutic serum * * * or analogous product," which have been produced at an unlicensed establishment and prohibits the false labeling of the containers of any such products. In this case petitioners were charged with having illegally transported and mislabeled dried normal human blood plasma. Petitioner Steinschreiber was sentenced to three months' imprisonment on each of counts 1–8

and 10–15, the sentences to run concurrently, with execution of the sentence suspended on count 1 and probation of two years to commence after completion of the prison sentence. Petitioner Calise was sentenced to six months' imprisonment on count 1, with four months of the sentence suspended, to be followed by two years of probation. Petitioner Westchester Blood Service, Inc., was fined $500. The court of appeals affirmed *per curiam* on the opinion of the district court, reported at 219 F. Supp. 373.[2]

Petitioners had moved to dismiss an earlier indictment on the ground that normal human blood plasma was not a product analogous to a therapeutic serum as charged in the indictment, and that if the statute was construed to encompass normal human blood plasma it would be void for vagueness. The district court denied the pretrial motion, noting that whether "as a scientific fact normal human plasma and therapeutic serum are analogous products * * * is a matter to be resolved on the trial by the expert and special knowledge of witnesses who may be called by the Government or by the defendants" (248 F. Supp. at 427). A similar motion to dismiss the present indictment (which superseded the earlier one) was also overruled before trial.

During the trial, over defense objection (*e.g.*, I R. 34–38, 48–49, 57–59), the government presented the testimony of three expert witnesses who stated that dried normal human blood plasma was a "product analogous to therapeutic serum" (*e.g.*, I R. 40–45, 67;

[2] The facts, which are not in dispute, are detailed in the opinion of the trial court (219 F. Supp. 373, 375–378).

II R. 67–70; 83–84). As one expert put it, plasma "is so analogous, is so close to being serum, that it practically is serum" (II R. 70). In its opinion at the conclusion of the trial, the district court made the following findings of fact: "that human plasma and human serum are identical * * * and that the only dissimilarity is that serum is plasma from which the fibrinogen, or clotting component, has been removed"; and that "[f]or many therapeutic uses plasma and serum are interchangeable * * * and the same constituent elements which are significant in such therapeutic uses are present in both," 219 F. Supp. at 382. The trial court further found that the legislative history of the statute and the regulations promulgated thereunder supported the view that Congress intended the statute to cover the manufacture and sale of normal human blood plasma, 219 F. Supp. at 382–383.

ARGUMENT

1. Petitioners' contention that Congress did not intend the terms "therapeutic serum * * * or analogous product" to embrace normal human blood plasma is refuted by the language of the statute, its legislative history and administrative interpretation.

In both the ordinary and scientific sense, the language of Section 351 embraces human blood plasma. In Webster's *Third New International Dictionary* (Unabridged, 1961 ed.) p. 1732, plasma is defined as "the fluid part of blood, * * * differing from serum essentially in containing the antecedent substance of

fibrin in addition to the constituents of serum".[3] The expert testimony at trial unanimously confirmed the scientific truth of this common definition (I R. 40–45; II R. 67–74; 83–85).

The legislative history of the statute and its administrative interpretation also support the view that the statute covers blood plasma. The Act was originally adopted in 1902, 32 Stat. 728, to insure the purity of those animal substances used in the "prevention and cure of disease" as were "introduced into the circulation directly" rather than by ingestion, since it was believed the former required more meticulous supervision of their manufacture and sale. See S. Rep. No. 1980, 57th Cong., 1st Sess. (1902), p. 2; H. Rep. No. 2713, 57th Cong., 1st Sess. (1902), p. 2. Normal human blood plasma fits in this category because it is administered directly into the bloodstream rather than into the digestive tract. The statute's failure to refer explicitly to blood plasma does not mean that Congress intended to exclude this product from the Act's coverage. Congress dealt with general classes—"virus, therapeutic serum, toxin, antitoxin,"—and concluded with the broad terms "or analogous product" so as to have the statute apply to subsequent scientific discoveries of new biological products for the "prevention, treatment or cure of diseases or injuries of man * * *." Hence the fact that human blood plasma was not in general use when the legislation was enacted in 1902

[3] As the trial judge pointed out, this dissimilarity is insignificant since a substantial portion of fibrinogen is precipitated out before plasma is used. 219 F. Supp. at 382.

does not affect the statute's current application to plasma.

The fact that Congress added arsphenamine—a product used in the treatment of syphilis—to the categories of covered products in 1944 and did not then enumerate human blood plasma in the statute (see Pet. 7a) is of no significance. At that time Congress was well aware of the fact that the Act was administratively construed to apply to normal human blood plasma. The regulations defined therapeutic serum as a "product obtained from * * * blood" ~~and further provided that a product was analogous "if composed of whole blood or plasma" [emphasis added]~~ (see 42 C.F.R. 73.1(i)(2), and 42 C.F.R. 73.1(i)(5)(ii), p. 4, *supra*).[1] Moreover, an official of the National Institutes of Health explicitly testified before Congressional committees before the passage of the 1944 Act that the NIH was licensing the preparation and distribution of human blood plasma.[1] Apart from the familiar principle that the views of an expert agency as to the meaning and scope of a statute it enforces are entitled to considerable weight (*e.g.*, *F.H.A.* v. *The Darlington, Inc.*, 358 U.S. 84, 90; *County of Marin* v. *United States*, 356 U.S. 412, 420; *Boutell* v. *Walling*, 327 U.S. 463, 471), the re-enactment of the statute in 1944 without material change reflects a Congressional affirmation of the settled administrative

[1] See Hearings Before the House Subcommittee of the Committee on Appropriations on The First Deficiency Appropriations Bill for 1943, 78th Cong., 1st Sess. (1943), p. 8; Hearings Before the House Subcommittee of the Committee on Appropriations on The Department of Labor—Federal Security Appropriation Bill for 1944, Part 2, 78th Cong., 1st Sess. (1943), p. 358.

interpretation. See *F.H.A.* v. *The Darlington, Inc., supra; National Labor Rel. Board* v. *Gullett Gin Co.*, 340 U.S. 361, 365–366.

There is no substance to petitioners' assertion (Pet. 7, 12–13) that, since the regulations define therapeutic serum as "the product obtained from the blood of an animal" human blood plasma cannot be an "analogous product." In the commonly understood biological sense, the term "animal" includes human beings. Likewise baseless is the argument that since regulations exist which deal with human whole blood and human packed red blood cells (42 C.F.R. 73.300 *et seq.*) the absence of any reference to human blood plasma reflects an administrative judgment that such plasma was not to be regulated by the statute. The inclusion of blood plasma in the definition of a product analogous to a therapeutic serum (42 C.F.R. 73.1(i)(5)(ii)) rendered unnecessary any further regulations relating specifically to plasma.

2. Petitioners accept the fact-findings of the trial court (Pet. 6), and thereby admit that they knew from the inception of their scheme that a license had to be obtained for the preparation and sale of blood plasma. 219 F. Supp. at 375. Notwithstanding this finding, they contend that neither the statute nor the regulations gave them sufficient notice that human blood plasma was covered by Section 351. As this Court recently observed in *United States* v. *National Dairy Corp.*, 372 U.S. 29, 33, "In determining the sufficiency of the notice a statute must of necessity be examined in the light of the conduct with which a defendant is charged." The facts in the present case

clearly support the district court's conclusion (219 F. Supp. at 382) that "* * * there is persuasive evidence that the statutory references to biological terms which may not have been initially clear to this court were in fact clear to these defendants at the time of the offenses charged in this indictment." Under the circumstances the petitioners' asserted constitutional claims are without merit.

3. There is also no merit to petitioners' contention that it was error to admit expert testimony that normal human blood plasma is analogous to therapeutic serum. Those dealing in medical products must be held to the technical definitions of statutory terms; otherwise the statute would be totally unenforceable. Moreover, the trial judge relied on uncontroverted scientific evidence and on the legislative history of the statute, as well as on the testimony of the experts. 219 F. Supp. at 382–383. Hence the decision as to the applicability of the statute was based upon his independent judgment, and not on the testimony of the experts only.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the petition for a writ of certiorari should be denied.

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